Project Number _____

THE FRAMINGHAM HEART STUDY

Biological Materials and Genetic Analysis Data Application and Proposal Form

NOTE: All proposals must be submitted by email to DNACoord@bu.edu
All sections of this application must be completed prior to review of the proposal.
An application that is not complete may be returned .
Sections I-V should be no more than 7 pages in length.

Date of Submission: _____

I. SUMMARY OF PROJECT:

Title of Proposed Project: _____
_____

Name of Project Director: _____ Tel: _____

Email: _____

Mailing Address: _____
_____

Institution/Company of Project Director: _____
_____
_____

Name(s) of other Professional Participants: _____
_____
_____

Institution / Company of each other participant: _____
_____
_____

Name of Framingham Investigators (if any): _____
_____

II. SCIENTIFIC RATIONALE

What are the objectives of this research and the background rationale which would justify these objectives? What are the estimates of heritability related to these objectives? Are there preliminary data that would support this investigation?

III. STUDY DESIGN, STATISTICAL METHODS AND POWER CALCULATIONS

A. What will be the study design?

B. What specific statistical methods will be used?

C. *What is the sample size for this project?*

D. *Provide power calculations which would show there is adequate statistical power for the hypotheses.*

V. PHENOTYPE DEFINITION AND AVAILABILITY

What are the phenotypes requested for this research? Describe specifically the information which is needed and the examinations which contain the required data. The web site http://www.nhlbi.nih.gov/resources/deca/elements.htm contains descriptions of all of the Framingham phenotypic data available for use in these research projects.

VI. GENETIC DATA

What genetic data currently available from the Framingham Study is needed for this research? The web site contains descriptions of the genome scan http://www.nhlbi.nih.gov/about/framingham/policies/fram.genetic.markers.pdf and candidate genes http://www.nhlbi.nih.gov/about/framingham/policies/fram.candidate.genes.pdf available from the Framingham Study.

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VII. REQUEST FOR BIOLOGICAL MATERIAL

Standard Plate Sets will provide 10 ng DNA per genotype requested. These plates are designed to test hypotheses relevant to the FHS mission in a set of unrelated individuals or in a set of biologically related subjects whose families were studied in a genome scan by the Mammalian Genotyping Service.

Customized DNA samples will be provided to allow typing of genes in order to test specific hypotheses. You will need to provide justification for these types of plate sets. Usually these samples will be prepared from cell-lines.

A. *What DNA is required?*

____ *Unrelated Plate Set: The current set is cell-lined based and contains more than 1800 specimens from biologically unrelated subjects.*

_____ *Family Plate Set: The current set is cell-lined based and contains more than 1400 members from the 330 largest pedigrees used in the Marshfield Genome Scan.*

____ *Customized Plates (**Provide full description of what samples you are requesting**.)*

If requesting customized plates, provide a justification for the need for these plates that cannot be addressed with the standard plate sets.

B. *Specify the amount of DNA needed per genotyping and the total amount per subject.*

If 10 ng DNA per genotype is not sufficient for your research provide a description and justification for a request for an increased quantity of DNA for each specimen requested to perform these studies:

C. *Describe the laboratory which will conduct the genotyping, the laboratory methods, and quality control.*

D.

E. *What genotyping will be performed? Provide a list of the planned typings in the following table. Include the candidate gene by NCBI Locus Link ID, HUGO name, STR's by HUGO name, SNP by dbSNP name, SNP maps by NCBI base positions (e.g. Chromosome 11, 69 Mb – 79 Mb) chromosomal location. Genes will be separately posted on the Framingham website in alphabetical order without identification of the researchers involved. Specific variants within genes will be posted when the typing is completed and returned to the Framingham Heart Study.*

Gene Name	Gene Description	Variants	Sample

Sample Table

Gene Name	**Gene Description**	**Variants**	**Sample**
ACE	Angiotensin I converting enzyme	D/I (deletion insertion	Unrelated Offspring

VII.

VIII. ABSTRACT

Provide an abstract of no more than 200 words describing the proposed research.
The abstract must include major hypotheses, an outline of laboratory methods and analytical approaches, and phenotypes to be studied. The abstract will be posted on the Framingham website when the projects are approved. Abstracts will posted with the name of the Project Director.

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IX. RECIPIENT ENTITY(IES):

Name and address of each Institution/Company whose investigators will receive access to requested:

a. Biological Materials:

_____
_____
_____

b. Genetic Analysis Data:

_____
_____
_____

and/or

c. Clinical Data:

_____
_____
_____

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IV. ADDITIONAL DOCUMENTS:

Return this form and include:

(1) Biographical Sketch (NIH format)
(2) IRB Approval (can be faxed)***
(3) any other supporting documentation

***This project requires an explicit review by IRBs at each institution involved. A statement from an IRB that this project is exempt is not acceptable.

Return by email to:

DNA Coordinator
Boston University Department of Neurology
DNACoord@bu.edu

Submission dates are January 15, April 15, July 15 and October 15. Applicants will be notified of the decision of the DNA Committee and the Research Committee within one month of submissions date.

Upon approval, the above-named Project Director will submit a Distribution Agreement to Boston University for the project. The Distribution Agreement Form can be obtained from the Framingham Heart Study website. The Project Director will be responsible for obtaining signatures on behalf of the Recipient Entities and returning the signed Distribution Agreement to The Framingham Study before Requested Materials will be released.